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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,145	10/19/2001	Michel Pairet	1/1174US	4148

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BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/086,145	Applicant(s) PAIRET ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *59 and 60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the restriction requirement submitted October 21, 2002 is acknowledged. Applicant's election without traverse therein of the invention of Group I, claims 1-58 and 61-66, and the species of beclomethasone and tiotropium salts are acknowledged.

Claims 59-60 are withdrawn from further consideration as being drawn to a non-elected invention. Claims 1-58 and 61-66, are herein examined on the merits in so far as they read on the elected species of beclomethasone and tiotropium salts.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7, 10, 32, 43, 45 and 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the antihistamine" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5-7 and 43 contain the trademark/trade names "GW215824", "KSR 592", "ST-126", "TG134a" and "TG227". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does

not identify or describe the goods associated with the trademark or trade name. In the present case, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 23-32, 39-40 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) in view of Banholzer et al. (USPN 5,610,163).

Nishimura et al. teaches an inhalation composition comprising oxitropium bromide and an inhalation composition comprising beclomethasone employed in treating asthma, see in particular pages 85-86. Nishimura also broadly teaches that the addition of inhaled anticholinergic agents (e.g., ipratropium bromide or oxitropium bromide) to corticosteroids has

been recommended in the treatment of asthmatic patients, see col.2 of page 85 and col. 1 of page 87 in particular.

Nishimura et al. does not teach tiotropium salts as anticholinergic agents, useful in asthma treating compositions. Neither does it teach a kit.

Banholzer et al. (USPN 5,610,163) teaches an inhalation composition comprising the anticholinergic agent tiotropium salt (e.g., bromide) useful in treating asthma, see abstract, claims 1 and 14 in particular.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ tiotropium bromide in lieu of ipratropium bromide or oxitropium bromide in the composition of Nishimura et al. and to incorporate the resulting composition in a kit.

One of ordinary skill in the art would have been motivated to employ tiotropium bromide in lieu of ipratropium bromide or oxitropium bromide in the composition of Nishimura et al. because tiotropium, like ipratropium and oxitropium, is an anticholinergic agent readily used in inhalation compositions useful for treating asthma. Note that the incorporation of a pharmaceutical composition into a kit with a set of instructions is within the purview of the Skilled Artisan and is therefore obvious.

Claims 13-22, 33-38, 41-58 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) in view of Banholzer et al. (USPN 5,610,163) as applied to claims 1-12, 25-32, 39-40 and 63-66 above and further in view of Gennaro et al. (*Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 1694-1699 and 1706-1707*).

Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) and Banholzer et al. (USPN 5,610,163) do not teach the employment of the specific propellants, excipients, co-solvents, lubricants and antioxidants herein. Neither do they teach the specific pH or particle sizes claimed herein.

Gennaro et al. (*Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 1694-1699 and 1706-1707, 1709*) teaches the employment of propellants (e.g., propane, butane, isobutene, fluorinated ethane and methane derivatives); antioxidants (e.g., ascorbic acid); co-solvents (e.g., water, ethanol, glycols); lubricants and dispersing agents in inhalers. It also teaches the particle sizes herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific propellants, excipients, co-solvents, lubricants and antioxidants, particle sizes herein, and to adjust the pH of the inhaler composition.

One of ordinary skill in the art would have been motivated to employ the specific propellants, excipients, co-solvents, lubricants and antioxidants, particle sizes herein, and to adjust the pH of the inhaler composition because the pharmaceutical necessities and the particle sizes employed herein are all known to be useful in inhaler compositions. Also, adjusting the pH in pharmaceutical compositions is within the purview of the Skilled Artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The

examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
November 14, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER